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Biomechanical Evaluation Of Locked And Non-locked Constructs Under Axial And Torsion Loading

A thesis submitted in partial fulfilment
of the requirements for the degree of
Master of Science in Engineering

By

VINIT PATEL
B.E., Ganpat University, India, 2006

2008
Wright State University

WRIGHT STATE UNIVERSITY
SCHOOL OF GRADUATE STUDIES

October 24, 2008

I HEREBY RECOMMEND THAT THE THESIS PREPARED UNDER MY SUPERVISION BY
VINIT ARVINDBHAI PATEL ENTITLED Biomechanical evaluation of locked and non-locked
constructs under axial and torsion loading BE ACCEPTED IN PARTIAL FULFILLMENT
OF THE REQUIREMENTS FOR THE DEGREE OF Master of Science in Engineering.

Dr.Tarun Goswami, Ph. D.
Thesis Director

Dr.S.Narayan, Ph. D.
Department Chair

Committee on
Final Examination

Dr.Tarun Goswami, Ph. D.

Dr.David Reynolds, Ph. D.

Dr.Michael Prayson, M. D.

Joseph F. Thomas, Jr., Ph.D.
Dean, School of Graduate Studies

ABSTRACT

Patel Vinit A. M.S.Egr., Department of Biomedical and Human Factor Engineering, Wright State University, 2008. Biomechanical Evaluation Of Locked And Non-Locked Construct With Axial And Torsional Loading.

Locking compression plates are proven to be safe for use in open reduction and internal fixation (ORIF). The ORIF is a procedure performed to treat fractures. It has various combinations of holes, the system provides more options for clinicians to use either locking screw or non-locking screws. This thesis investigates and determines the best construct with special locking and non-locking screws under both axial and torsion loading. Twenty femur constructs were assembled with 2 cm osteotomy gap between femur shaft and condyle, bridged with 4.5 mm - 10 holes condyle plates. Femurs were divided into 4 groups according to screw types and where they were placed. All screws were tightened to 4 Nm torque with a torque meter. Axial loads of -50 N to -700N and ± 5 degree rotation were applied for 50,000 cycles. Loosening torques of screws, stiffness and displacement of constructs were measured. Finite element analysis (FEA) was performed on locking plate and screws based on computed tomography images and Solidworks models. Analytical simulations were run under static and limited dynamic conditions were investigated with the experimental results. Axial load was applied and stresses induced were measured on the simulated models. Locking screw increased the torsional resistance of adjacent non-locking screw. Deformation and torsional stiffness in constructs with two locking screws were higher compared to one locking screw after 50,000 cycles. Locking screws increased flexibility of the constructs allowing reduction in osteotomy gap. FEA results show plate with locking screws induced lower von Mises stress compared to plate with non locking screws. This study concluded that among hybrid locked plated constructs, constructs with two locking screws provided more stability, flexibility and durability under various loading. A locking screw near the fracture gap increases axial and torsional strength of locking plated system and increased torsional strength of all the other screws.

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1

Introduction

Osteoporosis affects 24 millions of Americans specially women over 45 years of age [1]. Osteoporosis decreases thickness of bone and increases porosity, which cause bone fracture especially in hip and femur. It decreases the holding strength of the fixation devices (screws). Recent studies recommend use of locking compression plate (LCP) for osteoporotic bone fracture [2, 3]. Conventional plating system depends upon holding strength of bone material where LCP uses locking head screws which reduces construct's reliance on bone strength. LCP follows all AO (Arbeitsgemeinschaft Osteosynthesetragen) principles, creating a toggle free and fixed-angle construct. Minimally invasive plate osteosynthesis technique allows LCP to be inserted pain free avoiding open reduction and tissue damage [4]. LCP has lowered malunion rates in metaphyseal and diaphyseal fractures [5]. LCP also contains combination holes system which can house both types of locking and conventional screws. Many studies have been reported to test LCP stability under axial and torsion loading [6, 7, 8]. Data on the biomechanical and clinical performance of LCP are encouraging though cases of malunions have been reported. Failure by implant loosening, screw pull out, infections, crack development are usually seen [9, 10, 11]. Still few biomechanical factors such as a screw insertion torque, number and type of screw to be used, length of plate, which screw combination to use in hybrid plating technique, are unclear to clinicians.

This thesis explored relation between biomechanical properties of LCP and their

effects on LCP behavior. Both experimental and analytical tests were performed under axial and torsion conditions simulating in vivo conditions. Experimental analysis was conducted at Miami Valley Hospital, Dayton. 20 synthetic femurs with locking compression plate and screws were tested on EnduraTECH biomechanical test machine. Their insertion torque, loosening torque, axial and torsion stiffness, change in displacement were measured. Analytical testing was performed using 3D models created using MIMICS and Solidworks based on CT scan images. Finite Element Analysis was conducted using ANSYS applying axial loading on prepared simulated 3D models.

This thesis provides background information about bone fracture, treatment, locking compression plate and FEA analysis. Literature review of locking compression plate has been portrayed to create better understanding of fixation concepts and its biomechanical behavior. Experimental set up and analytical methods are described in experiments and methods and their results are presented in detail. Obtained results are discussed such as insertion torque, number of screws, screw type, screw placement to use in clinical settings.

2

Background

2.1 Bone Anatomy

Humans have 206 distinct bones in their skeleton system [12]. They are composed of collagen fibers impregnated with mineral salts. There are mainly three types of bone tissue: Compact tissue, Cancellous tissue and Subchondral tissue (Figure-2.1) [13].

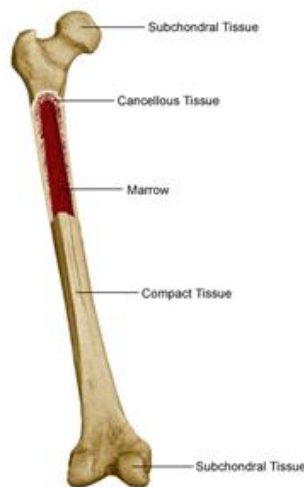


Figure 2.1: Anatomy of bone showing three bone tissues [13].

Compact tissue creates harder layer outside. Cancellous tissue is sponge-like which provides better elasticity to the bone. Subchondral tissue contains cartilage helpful to develop bones in children. Blood cells, blood vessels and nerves are enclosed in

the solid matrix. Compact and cancellous tissue together forms periosteum which produces canals and tunnels for blood vessels to pass and supplies nourishment to the bone. Bone provides shape and proper structural system for body movements. Also it stores the marrow and minerals, to develop blood cells [14].

2.2 Bone Fracture

Bone has potential to fail when applied a larger external forces. When large amount of impact occurs on bone, it loses integrity and fracture of bone occurs. The crack or break due to fracture makes a bone bleed and the swelling causes pain. Also nerve fibers surrounding the bone gets damaged. Bone fracture may occur due to diseased conditions like cancer or osteoporosis. Fracture can be divided in number of types.

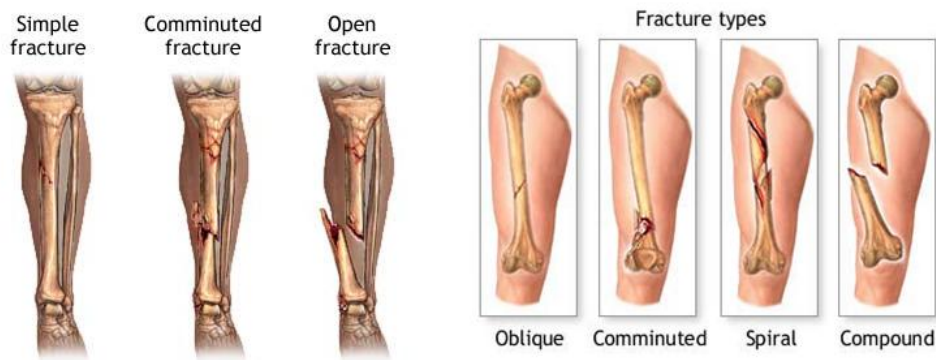


Figure 2.2: Types of fracture. Simple fracture are seen common where open fractures are hard to treat. Comminuted fracture requires insertion of fixation device. Where compound fractures can be healed with fixation plates [15,16].

As shown in Figure-2.2, simple fracture involves one fracture line through bone and compound fracture contains broken bone, which fragments out and penetrates the skin. Skin remains intact in closed fracture. Open fracture involves skin damage and bone fragmentation. Simple and closed fractures are easy to treat rather than multi fragmentary compound fracture [17]. Diseased fractures are called pathological fracture [18].

2.3 Bone Healing

Bone healing is a physiological process that restores the bone to its original shape. This process takes a varied time depending upon the fracture usually two weeks to two years [19]. Fracture healing restores tissue to its original physical and mechanical properties without creating any inflammation and damage to the surrounding tissue and organs. Healing occurs in three different phases: reactive phase, reparative phase and remodeling phase [20]. Reactive phase is subdivided in to fracture and inflammatory phase and granulation tissue formation phase. Reparative phase is subdivided in to callus formation phase and lamellar bone deposition phase.

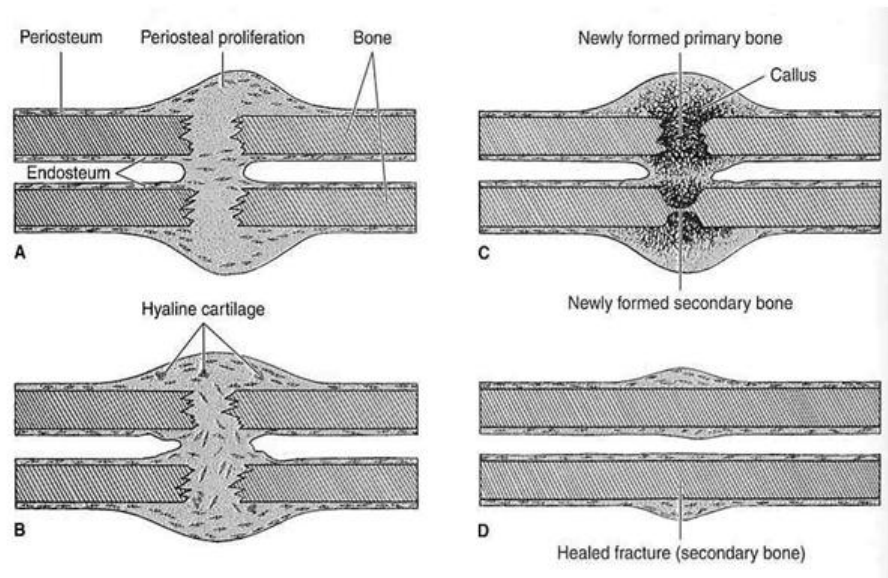


Figure 2.3: Bone Healing Process: (A) Fracture inflammatory stage where blood clotting occurred. (B) Granulation tissue formation. (C) Reparative phase where callus and lamellar bone develops. (D) Remodelling phase [20]

1. Fracture and Inflammatory Phase :

Within the hour of injury, blood cells within the damage tissue start to clot around the injured area and stop the blood bleeding. Extra vascular blood cells known as 'hematoma' causes the blood to clot.

2. Granulation tissue formation :

Adjacent to the injury area the fibroblast survive and start to infiltrate. They form a loose aggregate of cells with capillary sprouts, known as granulation tissue (Figure-2.3(A)).

3. Callus formation :

Granulation tissue keeps forming day after fracture. In the meantime cells of the periosteum also start replicating. The periosteum cells proximal to the fracture gap developed into chondroblasts and form hyaline cartilage. The periosteal cells distal to the fracture gap develop into osteoblast and form woven bone. Fibroblasts in the granulation tissue also develop into chondroblasts and hyaline cartilage. This tissue growth develops the new form of fracture bone known as the "fracture callus". As shown in Figure-2.3(C), callus is formed by connective tissue and cartilage tissue's combination. It temporarily binds and stabilizes bone.

4. Lamellar bone deposition :

With respect to the woven bone the bony substitution and hyaline cartilage passes through the process known as endochondral ossification and form the lamellar bone. Osteoblasts form the new lamellar bone upon the recently exposed surface of mineralized marix and start to form trabacular bone. This trabacular bone starts to restore the same bone's original strength.

5. Remodeling of the bone :

In this process trabacular bone starts to convert in to compact bone (Figure-2.3(D)). Shallow resorption pit known as "Howship's Lacuna" created by osteoclasts resorb the trabacular bone and eventually callus is remodeled in to the bone's original shape and strength [20].

2.4 Internal Fixation

During a fracture, bone passes through healing process, it also needs support to bear the load and movements of the body. Over the decades external fixation has been used to provide support from outside the body. It is easy and fast also non operative approach. It fails to heal the complex fracture or multi fragmentary fractures. In those cases internal support becomes necessary for the bone. AO was asked to list the most significant advances in the orthopedic treatment during 20th century and they ranked development in internal fixation high on the list [21]. Because of the development of the new biocompatible materials like stainless steel, cobalt-chromium and titanium alloys, internal fixation by metallic implants became feasible. Internal fixation devices work on the principle of load sharing. It provides support until bone is fully healed, or can be kept during the life time of a recipient. There are many types of internal fixation devices available in the market.

1. Wires and Pins:

Mainly used for the fracture of the small bones e.g. of the foot or hand where large fixation devices are difficult to insert.

2. Plates:

In case of metaphyseal fracture or too large bone fracture plates are useful. It works as the splint as external fixation device. It is inserted through the screws and fixation is achieved with the resistance force between the screw and plate.

3. Screws:

Screws can be implanted without plate to cure fracture. In any joint fracture or uneven surfaces like knee joint hip joint, pelvis etc, screws are easy option. Biodegradable screws are also available in the market so that second orthopedic surgery can be avoided.

4. Rods:

When bone weakens or loses its strength to sustain load, rods are inserted into the long bones to provide functional support.

2.5 Locking Compression Plate

Working as an internal fixator, locking compression is used to treat bone fracture with the anatomical reduction technique. It is a combination hole plate based on bridge conventional plate and PC-Fix internal fixation plate. LCP does not make contact with the bone reducing vascular damage. Locked screws do not allow screw toggling. LCP provides the rigid fracture fixation which is useful to heal osteoporotic bone fracture.

2.6 Finite Element Analysis (FEA)

Finite element analysis is a numerical method to find approximate solutions of the partial differential equations as well as of integral equations [22]. Finite element analysis was first developed in 1943 by R.Couraut [23]. From then it continues to develop. FEA is based on the numerical solution so it requires better computer. With super computers it's easy to get satisfactory results from the FEA tools. FEA uses a complex system of nodes and also with those nodes it makes a grid called mesh. Converting the mesh elements into small distributed area and finding mechanical properties of all the elements with FEM method. With the help of FEA structural, vibration, fatigue, heat transfer analysis are possible. It is an important tool mainly used in the new product design and existing product refinement programs..

2.7 CT Scan based Finite Element Analysis

CT scan imaging creates transverse slices of the object. All these slices contain the transverse properties of the object. If all these slices stacked from top to bottom, then joining them, it generates the surface 3D model of the object. With the help

of surface extraction technique and digital signal processing, perfect geometry of the object can be obtained [24]. This 3D model is transferred to FEA tool and can be analyzed.

3

Overview of locking compression plate

3.1 AO principle for internal fixation

A swiss group of surgeons began a study group called AO (Arbeitsgemeinschaft Osteosynthesetragen) in 1958 [25]. That group analyzed and exchanged information to improve the art of internal fixation. AO developed the four principles, summarized below, to achieve full, active and pain free mobilization of fractures.

1. Anatomic Reduction :

Fixation device should not affect the anatomic structure of the bone by creating unnecessary loads or friction.

2. Stable Fixation :

While fixed, fixation device must remain stable against external loads and movements, specially maintaining angular stability under torsional loading conditions.

3. Preservation of blood Supply :

Plate to bone contact should be kept minimal so that it doesn't interrupt the blood supply to the bone.

4. Early mobilization :

It must have proper environment and design to regain fixation as early as possible without creating inflammation.

3.2 Evaluation of LCP Plate

In 1895 about 110 years ago, Lane first developed the fixation plate for internal fixation but it failed because of corrosion [26]. Lambotte in 1909 and Sherman in 1912 continued Lane's work but failed to come up with better design [26]. Eggers's plate developed in 1948 failed because of screw sliding between two long slots [26]. Danis designed the plate that he called 'Coaptateur' in 1949. His revolutionary concept of fixation with compression influenced all the subsequent plate designs [26]. Muller in 1965 presented a design with the concept of intra fragmentary compression by tightening a tensioner [26]. In 1967 Schenk Willenegger developed the DCP (Dynamic Compression Plate) refreezing the Bagby and Jane's plate design [26]. Though DCP plate proved better because of its compression fixation still scientists were looking for improvements [27]. DCP did not provide enough rigidity and delayed union had been reported. Detectable fracture gap caused high stresses after plate removal. Compression plate (DCP) does not fit the bone anatomically resulting in the fracture dislocation. It does not allow the fixed angled screw to the fracture line. That introduces shear forces and loss of reduction. Cases of screw toggling had been seen consistently because of the secondary loss of reduction under axial loading [27]. DCP plate compressed the periosteum under the plate interrupting the blood supply to the bone. Overall DCP plates failed to assure AO principles. PC-Fix plates are narrow plates that have a designed undersurface which allows only points of the plate to be in contact with bone. It reduces the vascular damage of the bone allowing early bone healing [27]. PC-Fix was developed by Tepic. Two AO Principles, stable fixation and anatomic reduction, are not achieved fully with PC Fix plates [28,29]. LISS (Less Invasive Stabilization System) plates are developed specially to obtain the fracture healing of distal femur, supracondylar fracture and intra medullar fractures [30,31,32]. It contains the threaded screws with the thread plate hole. It was designed

to heal the long bone fractures like femur. In 1990 group of doctors from Davos of Switzerland developed the locking compression plate with combined concept of DCP, PC-FIX and LISS plate [33,34]. LCP plate contains the undersurface like PC-FIX plates and threaded hole like LISS plates. To improve the fixation, a combination hole system was designed in LCP plates. It can house both locking and non locking screws depending upon the fracture type and bone rigidity. LCP plates can be operated as DCP, LISS or combination hole plate. By making a correct choice in using LCP plates significant improvements in clinical outcomes can be achieved [35].

3.3 Locking Screw

Locking plates are designed such a way that it can house two types of screws locking and conventional screws. Four types of screws may be inserted on LCP, standard cancellous screw, standard cortical screw, self-drilling screws and self tapping screws [4]. Conventional screws function by pressing the plate to the bone and creating friction at the interface of plate and bone. Screws of conventional plate are subject to minimal bending load. Locking head screws does not press the body towards the bone, so it transfers more bending load then conventional screws.

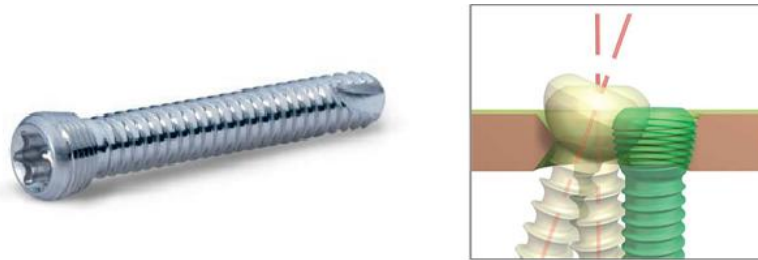


Figure 3.1: Locking screw with threaded screw head and self tapping drilling end (Left). Angular stability of locking screw compared to non-locking screws (Right) [36].

Screws can be either monocortical or bicortical [37]. Monocortical screw penetrates only one cortex of bone where bicortical penetrate through both the cortices. Generally self drilling screws are used as monocortical and self-tapping screws as bi-

cortical screws [4]. When bone is loaded, the bending force is applied on the screws which generates shear force. When axial load is more than friction force screws starts to toggle due to shear forces. The toggle depends on the contact between bone and plate, and quality of bone. Locking screws act as a spike fixed to the bone when load is applied not allowing screws to toggle [38].

3.4 Mechanics Of LCP Plate

Fixation in conventional plate depends on the friction acting between plate and bone. Generally this friction causes compressive load on fracture fragments and primary bone healing takes place [39]. As shown in Figure-3.2 force F_1 is generated by tightening screw and compressive force F_2 is generated on the bone. Due to these two loads friction force F_3 develops between bone and plate that leads to stable plate fixation. Plate and screw remain stable until axial force F_4 can't exceed friction force F_3 . The friction force F_3 is equal to the sum of torques on each of the screws. So the axial load F_4 is proportional to the sum of torques in each screw. As axial load F_4 increases, torque in screws starts decreasing, causing screw toggle, unstable plate fixation [40]. Locking plate and locking screw follow the all four AO Principle.

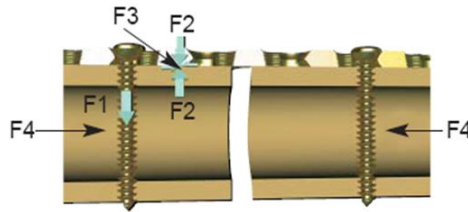


Figure 3.2: Mechanics of LCP plate [36]

Where,

F_1 - Force to tighten screw in to bone.

F_2 - Reaction force developed because of force F_1 .

F_3 - Friction force between plate and bone due to F_2 .

F4 - Axial load.

Once locking screws are engaged with the plate no further tightening is possible so implant locks in to the bone and does not allow any degree of anatomic reduction [41]. Locking plates allow the screws to be inserted perpendicular to the axis so it transmits the axial load over the length of the plate. It minimizes the toggling of the screw and provides absolute stability. Locking plate contains point-contact underface that reduces the compression of plate on to bone. That protects the periosteum and the blood supply to the bone is preserved [42]. As shown in Figure-3.3 LCP fulfilled all AO principles. Fixed angle construct and hybrid hole technique facilitates early callus formation and creates an environment for bone healing and early mobilization.

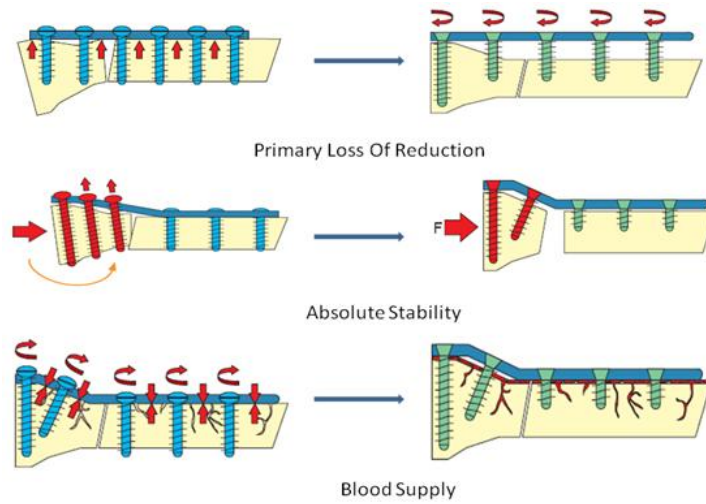


Figure 3.3: Locking plates gratify AO principles. (1) Primary Loss of reduction. (2) Absolute stability. (3) Preservation of blood supply under periosteum [36].

3.5 Factors affecting LCP Behavior

3.5.1 Plate material selection

According to the ASTM volume 04-012170-54, biocompatibility of the bone plate is the first clinical priority of the surgeons before implanting any device and biocompatibility of the implant depends upon the material selection [43]. For in vitro use

of implant, ASTM has decided certain standards. In-vivo conditions for any orthopedic implants are complex. For the orthopedic implant, commonly used materials are metal, ceramic, polymer, composites etc. Metal is the first choice for the internal fixation because of its high elastic modulus and excellent tensile properties. There are several factors to be taken care of before choosing material like corrosion, stiffness, Young's modulus, tensile strength, metal sensitivity etc.

Common disadvantage of metal is its corrosion behavior when implanted inside the body [44]. Metal ions and chemicals in tissue initiate the chemical reaction on implant surface causing corrosion. Most common cause of corrosion is difference of metals at plate screw interface [4]. Load bearing surfaces may also cause fretting corrosion. Plate screw interface corrosion is galvanic corrosion. Another factor is stiffness of the plate and screw. Plate faces static and cyclic loading in vivo which generates extremely complicated stress system in the device [45]. Stiff plate does not generate enough stress on the bone area making that part weaker than bone without plate. This phenomenon called as stress shielding and causes osteopenia [43]. So materials with good stiffness must be considered for use in bone plate. Materials with low modulus elasticity do not provide enough rigidity to the bone to heal the fracture and material with high elastic modulus increases rigidity and stresses. Stainless steel and titanium alloy (Ti-6Al-4V) are two ASTM certified materials used for locking compression plate [45,46,47,49]. Stainless steel is strong, cheap, biocompatible, and relatively ductile. In recent times use of devices made of Cobalt-Chromium-Molybdenum is growing because of its higher corrosion resistance and high strength. But they are very expensive and toxic in ionic form. For the fixation devices stainless steel remains the best choice. Stainless steel contains chromium and nickel, which cause adverse, toxic or carcinogenic reactions when these ions come in contact with body fluid, but with latest technologies these effects are minimized.

Figure 3.4 shows the chemical composition of several stainless steels and titanium alloys. Preoperative adjustment or bending of the plate causes damage to the plate which increases the corrosion risk. It is still unclear that hypersensitivity response to

Group	Co	Cr	Ki	Mo	W	Ti	Al	V	Cu	Mn
F 75 cast Co/Cr/Mo alloy	59–60%	27–30%	<1%	5–7%	N/A	N/A	N/A	N/A	N/A	1%
F 90 wrought Co/Cr/Mo alloy	~45%	19–21%	9–11%	N/A	14–16%	N/A	N/A	N/A	N/A	N/A
F 799 forged Co/Cr alloy	~59%	26–30%	<1%	5–7%	N/A	N/A	N/A	N/A	N/A	N/A
F 562 wrought Co/Ni/Cr alloy	~29%	19–21%	33–37%	9–10%	N/A	N/A	N/A	N/A	N/A	N/A
F 1537 wrought Co/Cr/Mo alloy	~59%	26–30%	<1%	5–7%	N/A	N/A	N/A	N/A	N/A	N/A
SM 21 Co/Cr alloy	58.9–69%	26–30%	<1%	5–7%	N/A	N/A	N/A	N/A	N/A	N/A
ASTM F138 stainless steel	N/A	17–19%	13–15.5%	2–4%	N/A	N/A	N/A	N/A	0.5	N/A
ASTM F136 titanium alloy	N/A	N/A	N7A	N/A	N/A	89–91%	5.5–6.5%	3.5–4.5%	N/A	N/A

Figure 3.4: Composition of stainless steel and titanium alloy [4, 51].

metallic biomaterial affects implant performance. As use of metal increases, further investigation is required to solve this problem [50].

3.5.2 Fracture type

Another factor associated with the plate performance is the fracture type. Selection of type of the plate is the major consideration for surgeons before implanting fixation plate. Gautier and Sommer defined guidelines for clinical application of the LCP [52].

As shown in Figure 3.5, concept of plate is used depending upon the fracture type. Conventional compression plate performs well for normal quality of bone and fracture with normal or partial contact between fragments. When both ends of bone fragments are not in contact with each other, bridge plate technique can be used either with locked or standard screws based the bone quality. Combination technique is employed for simple oblique or articular fracture with more standard screws and less number of locking screws. LCP is widely utilized for diaphyseal or metaphyseal fracture with poor bone quality (e.g. osteoporosis).

Selection of LCP plates also depends upon the type of fracture and bone. Different sizes of plates are used for different bones. For femur fracture fixation 4.5/5.0 LCP plates are used whereas for acetabular fractures, 3.5 LCP plates are used [52]. Also depending upon the distal and proximal dimension of bone, a plate is chosen e.g. 4.5/5.0 LCP metaphyseal. There are many other plates available depending upon

Concept	Technique	Screws Type	Fracture Type	Bone Quality
Compression plating technique	DC-principle	Standard eccentric and standard neutral Standard eccentric and locked	Full or partial contact between main fragments	Normal
	Tension device	Standard alone, Locked alone Standard and locked	Full or partial contact between main fragments	Normal
Bridge plating technique	Distractor, Fracture table	Standard neutral	No contact between main fragments	Normal
	Distractor, Fracture table	Locked	No contact between main fragments	Poor or normal
Combination technique	DC-principle and bridge plate technique	Standard eccentric and locked	Segmental fracture one level simple, one level comminuted fracture pattern	Normal or poor
	Plate lagging screw in meta- or diaphyseal bone segment	Standard and locked	simple oblique fracture	Normal or poor
	Plate lagging screws for articular fragment	Standard and locked	Articular fracture	Normal or poor
Hybrid use of both types of screws	Reduction onto the plate	Locked and standard	Diaphyseal or metaphyseal fracture	Normal or poor
	Malalignment of the plate on bone axis	Locked and standard	Diaphyseal or metaphyseal fracture	Normal or poor

Figure 3.5: Selection of plate concept depends upon Fracture type and Bone Quality [52]

fracture type [52].

3.5.3 Plate Length

MIPO (Minimally Invasive Plate Osteosynthesis) was developed to minimize the soft tissue damage and decrease non-union or infection. Before MIPO short plates were used to reduce tissue damage. But with use of MIPO technique, a small incision is required to place plate and biomechanical behavior was given more priority in reserch. Plate length is dependent on fracture length and loads being applied to the plate (e.g. bending, pull out) [4]. The ratio of plate length to fracture length is called plate span width. [56].

Guatier and Sommer recommended plate span width 2 to 3 for comminuted fracture and 8 to 10 for simple fracture [52]. This suggests that for more comminuted fracture, a long plate provides better axial and torsion stability than short plate [53]. Working length is the length between two screws of two different fracture fragments

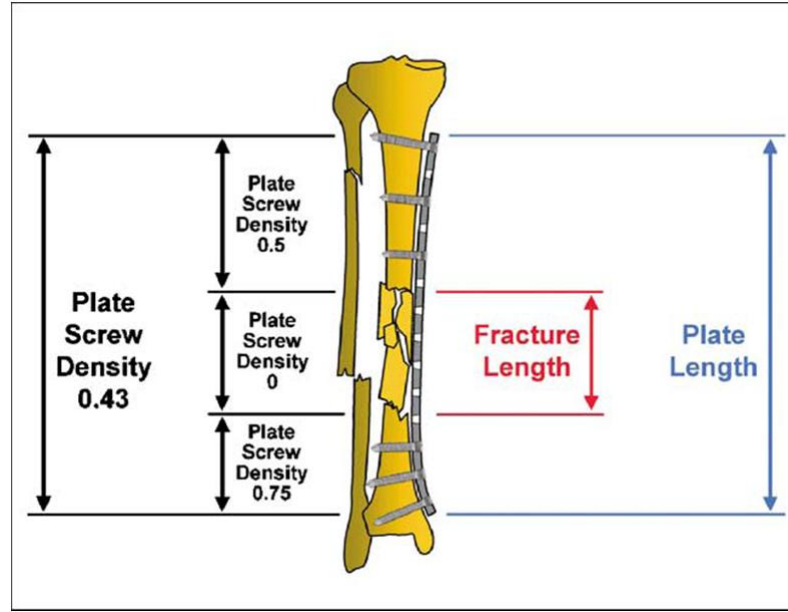


Figure 3.6: Relation between plate length and fracture length. Plate screw density defined as number of screws per number of holes in the fracture segment. Total plate screw density is 0.43, which is 6 screws divided by 14 holes [4].

(Figure-3.6). As fracture length is small, working length will be small, so that bone ends do not come in contact with each other reducing callus formation [54]. More stresses induced and strain increased during torsion loading as shown in Figure-3.7.

Stresses induced in the plate with 6 mm fracture gap are higher than plate with 1 mm fracture gap. Even stresses in the screw decrease with smaller fracture gap [53]. Stoeffel's FEA study suggests same results.

3.5.4 Screw type and performance

As mentioned earlier two types of screws are available, monocortical and bicortical. Selection of type screw depends upon bone type, fracture type, plate type and applied loads. Working length of the screw is shown in Figure-3.8[52]. In osteoporotic bone working length is small because of small bone thickness compared to normal bone. Locking screws are always the choice for osteoporotic bone because of its angular stability [8, 52]. Small working length decrease torque resistance of the screw and

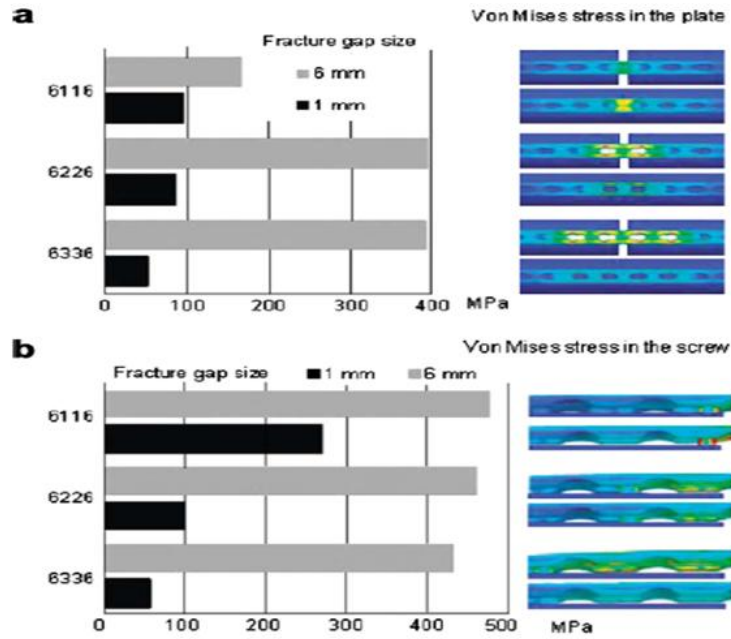


Figure 3.7: (A) FEA study suggest stresses induced in 6mm fracture gap size plate is higher (B) stresses in screws are also higher in 6mm fracture gap plates [53]

it easily failed in torsion loads [4]. Compared to bicortical screw monocortical screw has small working length that decreases the torque resistance. When torsion load is applied, chances of screw pullout increase. Length of monocortical screw must be kept less than bone diameter otherwise the screw end directly comes in contact with opposite side of cortex.[52].

Bicortical screw penetrates both the cortices so it increases the torque resistance. For osteoporotic bone bicortical screws provides more strength. Bicortical screw possesses sticking out length, which needs to be taken into consideration during implanting that it should not damage the neurovascular system. MIPO allowed biocortical screw insertion easily. For clinicians, choosing a screw type, screw location and number of screws to use become important considerations. Studies related to these will be covered in chapter 6.

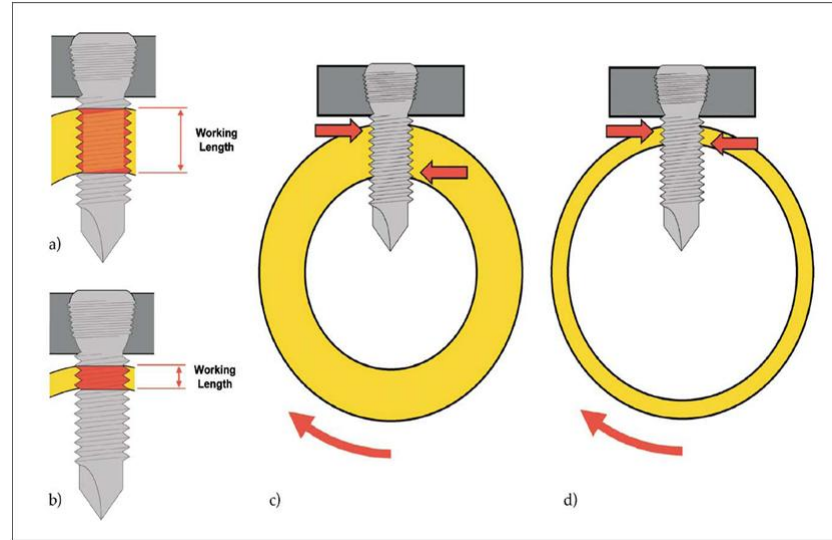


Figure 3.8: (a.c)- for normal bones, working length is higher. (b-d) for osteoporotic bone as thickness of the bone decrease working length is small and torque resistance to torsion load decrease. (e). Length of the monocortical screw should not go higher than bone diameter [52].

3.5.5 Clearance

LCP plates have point contact undersurface preserving periosteum blood supply. Conventional plates exert 2000-3000N force when screws are tightened to bone [37]. LCP plates reduce this load and preserve the blood supply. Reduced contact between bone and plate also improve the bone growth [55]. But recent studies started researchers to consider the maximum and minimum distances between plate and bone. Ahmad et al.(2007) experimented on four constructs with different clearance between plate and bone [7]. They used DCP plate flush with the bone. Similarly a second construct was prepared with LCP plate. For third and fourth construct LCP plate was fixed at distances of 2mm and 5 mm respectively from bone (Figure-3.9).

Two types of tests were performed for each construct. For dynamic testing axial load of 5-250 N with rotational load of 5 N/s. In the static loading test, incremental load of 100 N was applied until failure had been achieved. Similarly 0-5N was applied over 1000 cycles if failure did not occur. As shown in Figure-3.10, LCP with 5mm clearance requires less axial load to fail compared to LCP flushed plate. Also LCP

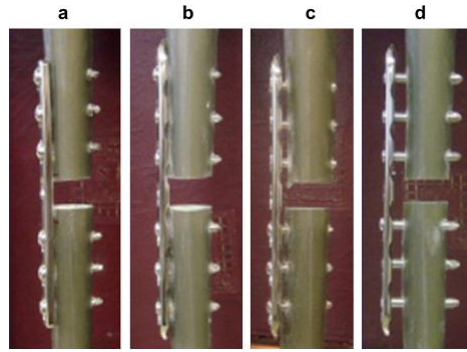


Figure 3.9: Experimental setup of the mechanical study conducted with four different construct. A) DCP flush plate B) LCP flush plate C) LCP at 2mm from bone D) LCP at 5mm from bone [7].

flushed plate shows better result than DCP plate. Under cyclic loading displacement and deflection of LCP with 5 mm is far higher than LCP flushed plate. From the study they recommended to place the plate less than 2 mm distance and do not flush it on to bone to preserve periosteum blood supply [7]. Stoffel suggested that by increasing distance of plate 2 mm to 6 mm from bone axial and torsional stability decreased by 10-15% [53].

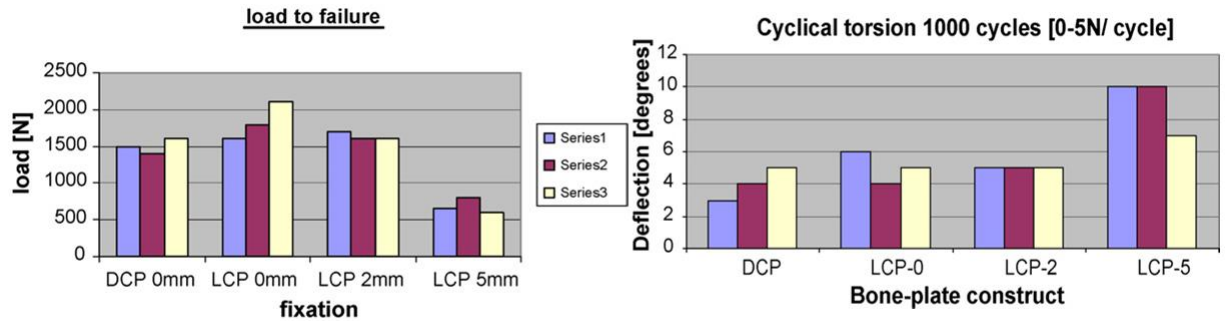


Figure 3.10: (A). Axial load to fail for LCP plate with 5mm distance is higher than LCP-O. (B)at the end of 100 cycles LCP-5 shows higher deflection than LCP-0 [7].

4

Experiments and methods

To evaluate biomechanical behavior of locking compression plated constructs, experimental program was undertaken by testing and analytically developed simulations.

4.1 Biomechanical testing at Miami Valley Hospital

Experimental testing was conducted at biomechanics laboratory located in Miami Valley Hospital, Dayton.

4.1.1 Materials used for testings

Femur shaft as shown in (Figure 4.1) were prepared from epoxy glass fiber made of shallow cylinder filled with polyethylene (Model 3403, Pacific research Laboratories, Vashon, USA). These synthetic femurs were used simulating an osteoporotic bone. Osteoporotic femurs were tested to observe their behavior when LCP plates were applied. To fit femur firmly in to the grip under torsion loading, femur shaft simulated by a cylinder was used instead of full femur. This shaft has density of 1.64 gm/cm^3 and compressive strength of 157 MPa (Sawbones worldwide). It has an elastic modulus of 16 GPa and Poisons' ratio of 0.22 (Sawbones Worldwide). The distal part of the femur contained a condyle as shown in Figure 4.1. It is made of same material as shaft. Fracture gap (Osteotomy gap) between condyle and shaft was kept 2 cm.

The devices were supplied by Synthes, PA and were $4.5 \times 10 \text{ mm}$. These devices



Figure 4.1: Construct prepared for Biomechanical testing with femur shaft, condyle, 10 hole 4.5 mm LCP plate and 8 locking or non-locking screws.

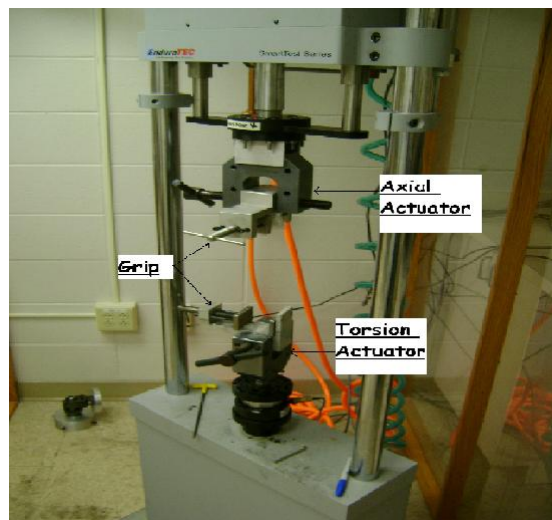


Figure 4.2: EnduraTEC BOSE machine for mechanical testing at Miami Valley Hospital, Dayton. Two Actuators with holding grip is shown.

were used to connect the fracture gap between condyle and shaft. These plates are designed to heal condyle fracture, osteoporotic bone fracture, malunions and nonunions of the distal femurs etc. Plate's head was anatomically shaped to match the shape of condyle and have six locked screw holes to provide support structure for entire fracture gap. The plate head accepts the 5.00mm canulated locking screws (synthes, PA). Four locking screws were inserted in all 20 femurs' condyle parts as shown in Figure 4.1. Combination of 4 mm locking screws and 4.5 mm cortex(non-locking)screws were arranged to fix shaft with LCP plate. Condylar LCP plates were 278 mm long and made of 316L stainless steel material. All the screws were of the same material. As shown in Figure-4.2, EnduraTEC Smart SP from BOSE biomechanical testing machine was used for experimental program. It uses Wintest control system which allows time control, integrated data control and multichannel control. Bottom actuator controls torsion command and top actuator provides axial command. Additionally, two grips were designed (Figure-4.2) for the testing of the femur which held specimens firmly for both axial and torsion tests as a part of this research.

4.1.2 Loads

Construct was fixed in the EnduraTEC machine shown in Figure-4.5. Axial load was applied on the femur shaft through axial actuator and torsion load was applied to the condyle through bottom actuator.

Axial load applied on the shaft was sine wave. Upper limit was kept at -50N and lower limit at -700N. Normal load on the femur head was simulating the weight bearing of a 70 kg person. Torsion load waveform was sinusoidal and its' limit was kept -50° to 50° . Rotation of the condyle signified the internal and external rotation of the femur during normal gait cycle which is 100° as shown in Figure 4.3. This whole movement characterized external and internal rotation of the femur during normal gait cycle.

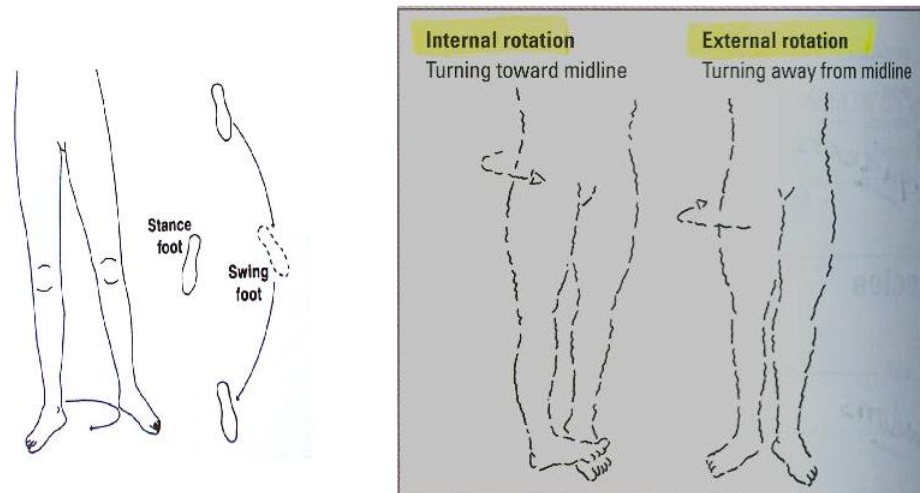


Figure 4.3: Rotation movement of leg and femur during normal gait cycle. It can be either internal rotation or external rotation.

4.1.3 Groups and constructs

A total of 20 femur constructs was prepared and tested during the study. According to the screw placement and screw type, all the 20 femur constructs were divided in four groups. All the groups and their screws were listed in Table-4.1. Five femurs were plated for each of the 4 groups. Four locking screws were inserted in the condyle as shown in Figure-4.4. Fracture gap was kept 2 cm in all the femur constructs. Four screws were inserted in shaft through locking plate. Screw-1 was inserted in the first hole from the bottom of the osteotomy gap. Screw-2 is in the third, screw-3 in the sixth and screw in the eighth hole for the entire 20 femur construct as shown in Figure-4.4. Table-4.1 explains which screw type was inserted at which location in the shaft. Initial torque of all the screws was kept 4 N.m except 3rd femur set in all groups.

4.1.4 Test setup

As discussed earlier femur shaft was gripped on the axial actuator and condyle on the rotation actuator. Axial load of -50 to -700N and rotation of $+5^\circ$ to -5° was

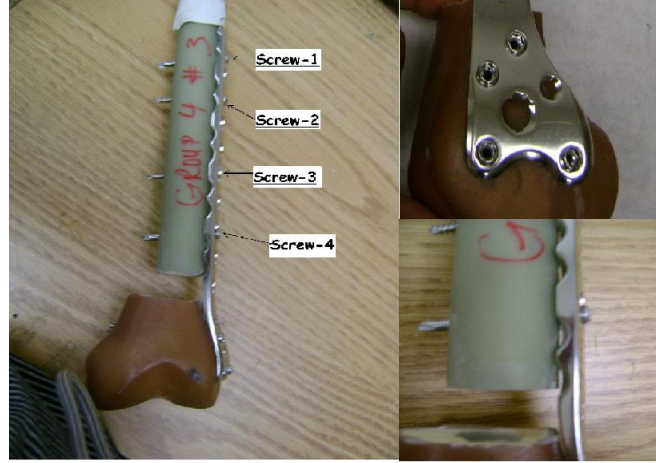


Figure 4.4: For femur shaft top screw is noted as screw-1, bottom as screw-4, center two screw as screw-2 and screw-3. 4 locking screws on the condyle remained same for all constructs. Fracture gap was kept 2 cm for all constructs.

GROUP	FFMUR NO.	screw-1	screw-2	screw-3	screw-4
1	1,2,3,4,5	Non Locking	Non Locking	Non Locking	Non Locking
2	1,2,3,4,5	Non Locking	Non Locking	Non Locking	Locking
3	1,2,3,4,5	Locking	Non Locking	Non Locking	Non Locking
4	1,2,3,4,5	Locking	Non Locking	Non Locking	Locking

Table 4.1: 20 femur constructs divided in four groups according to their screw location and type

applied for 50,000 cycles with sine wave of frequency 2 Hz. Limit of 0 to -750N was set for axial command and $+10^\circ$ to -10° for rotation command.

Tests stopped if they crossed the set limit. If screws got failed or shafts broke, it induced more displacement and specimen crossed the set limit. The tests ran for 50,000 cycles. Data was acquired at every 250 cycles. Reading of displacement, load, torque and rotation degree was taken from data acquisition system. At the end of cyclic tests 50,000 cycles, loosening of torque was measured in all the screws. A torque meter manufactured by Sharp was procured for this study. From the test data, stiffness and displacement had been calculated and plotted for all the groups.



Figure 4.5: Construct fixed in the machine. Femur Shaft was tightened by axial grip and condyle was fixed through torsion grip.

4.2 Analytical Testing

Second part of the study involved the analytical testing of the locking compression plated femur constructs. This testing was performed in steps shown in Figure-4.6.

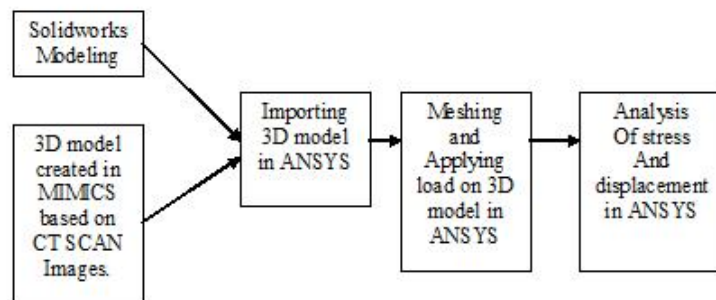


Figure 4.6: Flow diagram of the steps to perform analytical testing.

4.2.1 Solidworks Modeling

Solidworks is a 3D modeling software used to create 3D parts in all different planes. Plate was created in the solidworks with same dimensions as synthes condyler 10 hole plates that were used for biomechanical testing. To analyze the plate only one hole was taken in to consideration instead of combination hole system (Figure-

4.7(A)). So, locking and non locking holes were constructed same way. It is difficult to mesh threads inside screw hole so all the locking screws holes were designed without threads. Locking screws and Non-locking screws were designed without threads to decrease geometrical errors during meshing in ANSYS.

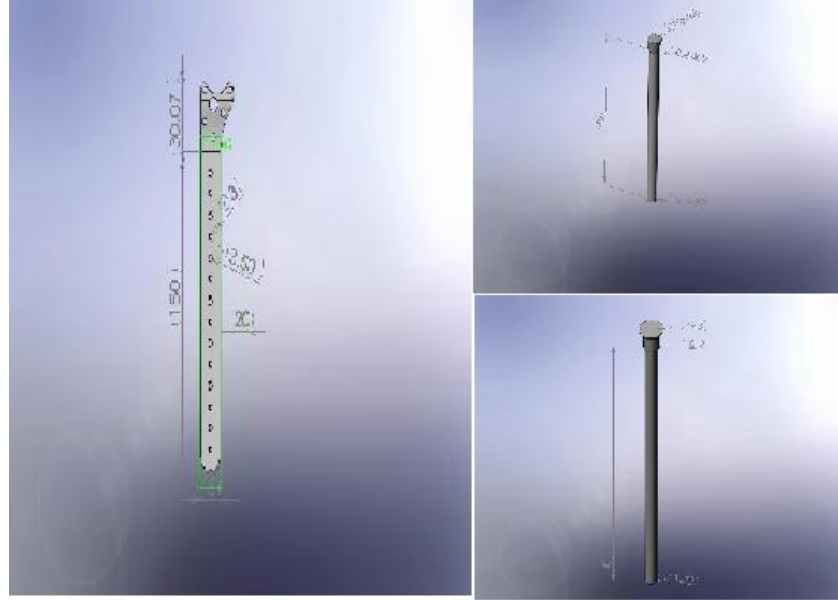


Figure 4.7: (A) 3D model of solidworks model. (B) 3D model of Locking and Non-locking screws.

Head of the screw for non-locking screw was kept small to decrease its contact with the plate hole as shown in Figure-4.7(B). Condyle part was designed with loft and fillet operation as shown in Figure-4.8. Assembly was created joining all these models (Figure-4.8). This assembly looks similar to the femur construct tested experimentally. Condyle part and femur shaft had been removed for further analysis in ANSYS and constraints were set on the plate head and on the screw (Figure-4.8). Model was then saved in parasolid format.

4.2.2 MIMIC Models

Mimics is a 3D modeling software that imports the CT/MRI imaging data. CT scan data of femur construct were taken at Miami Valley Hospital, Dayton. 3D models

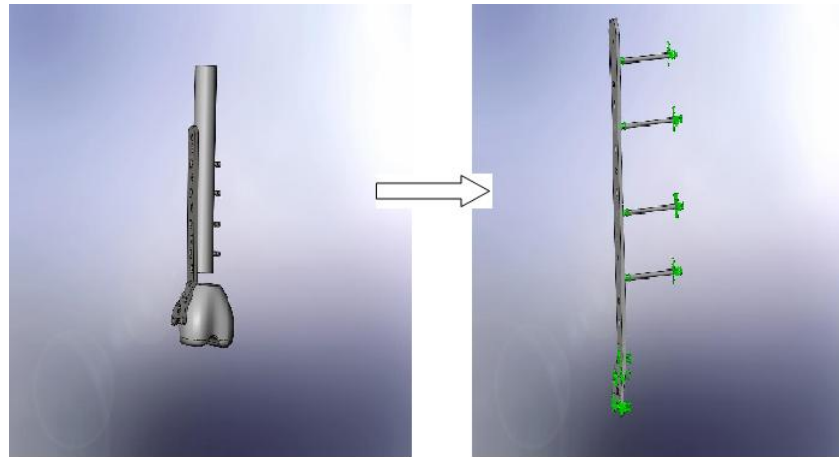


Figure 4.8: To analyze model in ANSYS, femur shaft and condyle was replaced by constant.

of the construct were prepared using Mimics tools. As shown in Figure 4.9 CT cross section contains scattering due to metal artifact and resulting noise of the plate and the screw. The noise was manually minimized in Mimics. Models similar to anatomical model were achieved using remesher tool as shown in Figure-4.9. Mimics provides only surface mesh. Surface mesh was stored in Ansys supported format. In Ansys, it was opened using read input file. It was difficult to generate volume mesh in Ansys based on surface mesh. Surface mesh automatically takes SHELL 93 element. Surface mesh does not provide displacement.

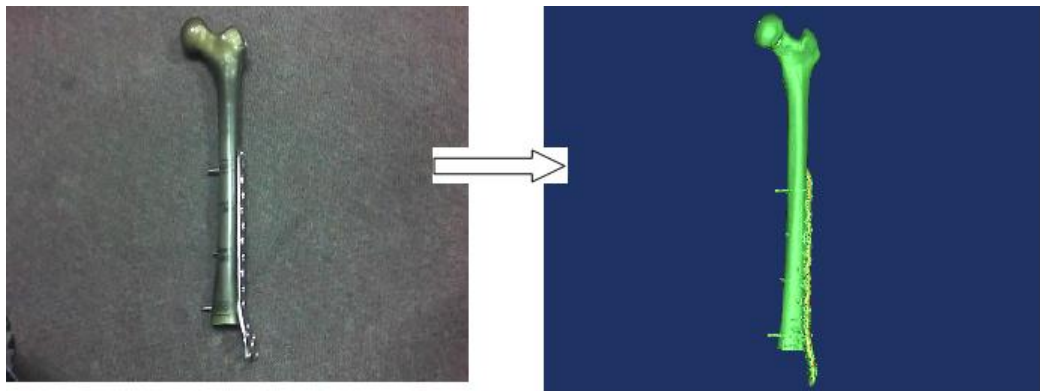


Figure 4.9: Mimics Model on right created from CT scan images of femur construct on left.

4.2.3 FEA analysis in ANSYS

Solidworks model stored in parasolid format were imported in Ansys. Element type SOLID187 was applied to all components. Stainless steel 316 L property was assigned to plate and screw. Elastic modulus of 193GPa, poisson's ratio of 0.33 and density of 8000 Kg/m³ was assigned in material property. Free mesh was done for all volume as shown in Figure-4.10. Loads are applied on screws and it is constrained at bottom of plate and on all screws. Time harmonic mode was selected for analysis type. Loads were applied for 100Hz with 300N load on each screw in negative Y direction (Downward). Frequency in harmonic mode represents the number of cycles test runs and here 100Hz was selected so all test ran for 100 cycles. Results were viewed in plot control with changing read result to frequency. Harmonic tests provide all the results with respect to frequency but to analyze displacement and stress properties, results converted with respect to time.

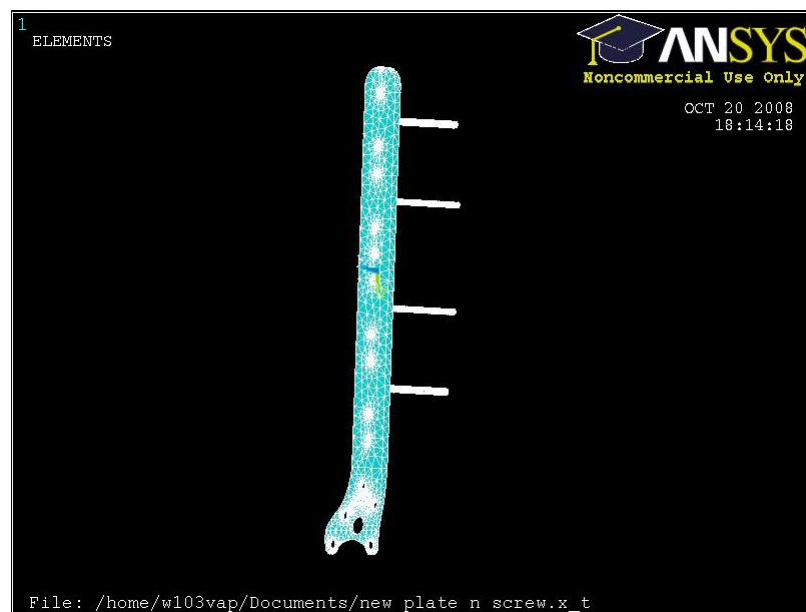


Figure 4.10: Meshing of 3D model Created in Solidworks.

5

Results

Wintest software installed with the EnduraTEC machine acquired the data. Two hundred scan points were taken through 50,000 cycles. Scan points were examined at every 5000 cycles. Stiffness and deformation were calculated and plotted from selected scan points. Table-5.1 shows summery of loosening torque at every screw position for each of the femur constructs. Table 5.2 shows the average loosening torque, average stiffness, average deformations and test result of group-1 and 2 constructs, and Table 5.3 for groups 3 and 4, respectively.

5.1 Loosening Torque

Figure 5.1 shows the differences between the loosening torque of four groups. After the tests were completed the average torque in group-1 (non-locking construct) screws was 0.56 Nm whereas group-2 was 2.72 Nm (semi-locked construct). The locked construct group-4 demonstrated 2.67 Nm torque after testing. The data were analyzed statistically with the Kruskal Wallis test, one-way Annova test and Tukey-Kramer HSD (Figure 5.1(D,E)). Comparable results were obtained with one-way Annova. The Tukey-Kramer HSD results suggest similarities between group-2 and group-4 and significant differences between groups 3 and 4.

Loosening torque mechanics of non locking screw and locking screw is different so comparison of loosening torque in both screws was also done separately. Figure 5.1(A) shows the average loosening torque of all locking screws in groups 2, 3 and

FEMUR TYPE	Looseing Torque in SCREW-1 (Nm)	Loosening Torque in SCREW-2 (Nm)	Loosening Torque in SCREW-3 (Nm)	Loosening Torque in SCREW-4 (Nm)
Group-1 Femur-1	0	2.59	1.58	0.2
Group-1 Femur-2	0	0	0	0
Group-1 Femur-3	0	0	0	0
Group-1 Femur-4	2.5	0.79	2.53	1.103
Group-1 Femur-5	0	0	0	0
Group-2 Femur-1	3.358	2.298	3.375	2.923
Group-2 Femur-2	2.5	3	0	2.03
Group-2 Femur-3	2.9	3	3.6	1.6
Group-2 Femur-4	2.58	3	3	3.71
Group-2 Femur-5	2.6	3	3	2.6
Group-3 Femur-1	3.6	2.6	2.6	3.38
Group-3 Femur-2	3.538	1.39	1.29	0.41
Group-3 Femur-3	0	0	0	0
Group-3 Femur-4	4	2.11	2	0
Group-3 Femur-5	2.6	0	0	0
Group-4 Femur-1	2.592	3.399	1.983	3.322
Group-4 Femur-2	2.57	2.39	2.049	2.56
Group-4 Femur-3	1.56	0	2.83	0.284
Group-4 Femur-4	3.31	2.28	3.37	1.366
Group-4 Femur-5	2.6	2	3.2	3.9

Table 5.1: Loosening torque at each screw position after test completed.

Femur Construct	Average Loosening Torque (Nm)	Percentage Loosening Torque (%)	Average Axial Stiffness (N/mm)	Average Torsion Stiffness (Nmm/° Rotation)	Average Deformation (mm)	Test Results Observations
Group-1 Femur-1	1.09	72.68	2400	51.79	0.35	Completed 50,000 cycles with out any failure.
Group-1 Femur-2	0	100	1181.3	92.6	0.49	Failed at 44,365 cycles with highest screw sheared.
Group-1 Femur-3	0	100	398.5	334.8	0.54	Failed at 26,923 cycles with three screws broken.
Group-1 Femur-4	1.73	56.75	603.6	175.6	0.74	Completed 50,000 cycles with out any failure.
Group-1 Femur-5	0	100	1022.6	118.8	0.78	Failed at 40,721 cycles with lowest screw sheared.
Group-2 Femur-1	2.99	25.25	796.4	136.8	0.325	Completed 50,000 cycles with out any failure.
Group-2 Femur-2	1.88	53	555.1	168.2	1.12	Completed 50,000 cycles with out any failure.
Group-2 Femur-3	2.78	30.5	968.8	115.6	0.59	Completed 50,000 cycles with out any failure.
Group-2 Femur-4	3.07	23.25	812.8	147.2	0.82	Completed 50,000 cycles with out any failure.
Group-2 Femur-5	2.8	30	593.6	346.4	0.92	Completed 50,000 cycles with out any failure.

Table 5.2: Results of femur constructs of groups 1 and 2

Femur Construct	Average Loosening Torque (Nm)	Percentage Loosening Torque (%)	Average Axial Stiffness (N/mm)	Average Torsion Stiffness (Nmm/° Rotation)	Average Deformation (mm)	Test Results Observations
Group-3 Femur-1	3.045	23.87	629.8	165.6	1.46	Completed 50,000 cycles with out any failure.
Group-3 Femur-2	1.66	58.5	1213	78.7	0.3	Completed 50,000 cycles with out any failure.
Group-3 Femur-3	0	100	245	345.8	0.73	Completed 50,000 cycles but construct failed at lowest screw.
Group-3 Femur-4	2.03	49.25	455.9	167.4	1.46	Completed 50,000 cycles with out any failure.
Group-3 Femur-5	0.65	83.75	556.4	238.8	0.97	Completed 50,000 cycles with lowest screw pulled out.
Group-4 Femur-1	2.92	27	593.3	167.4	1.34	Completed 50,000 cycles with out any failure.
Group-4 Femur-2	2.39	40.25	337.3	331	1.062	Completed 50,000 cycles with out any failure.
Group-4 Femur-3	1.84	54	4011.2	27.67	0.058	Completed 50,000 cycles with out any failure.
Group-4 Femur-4	2.58	35.5	584.2	203.9	1.174	Completed 50,000 cycles with out any failure.
Group-4 Femur-5	2.925	26.87	630.5	366.4	2.538	Completed 50,000 cycles with out any failure.

Table 5.3: Results of femur constructs of groups 3 and 4

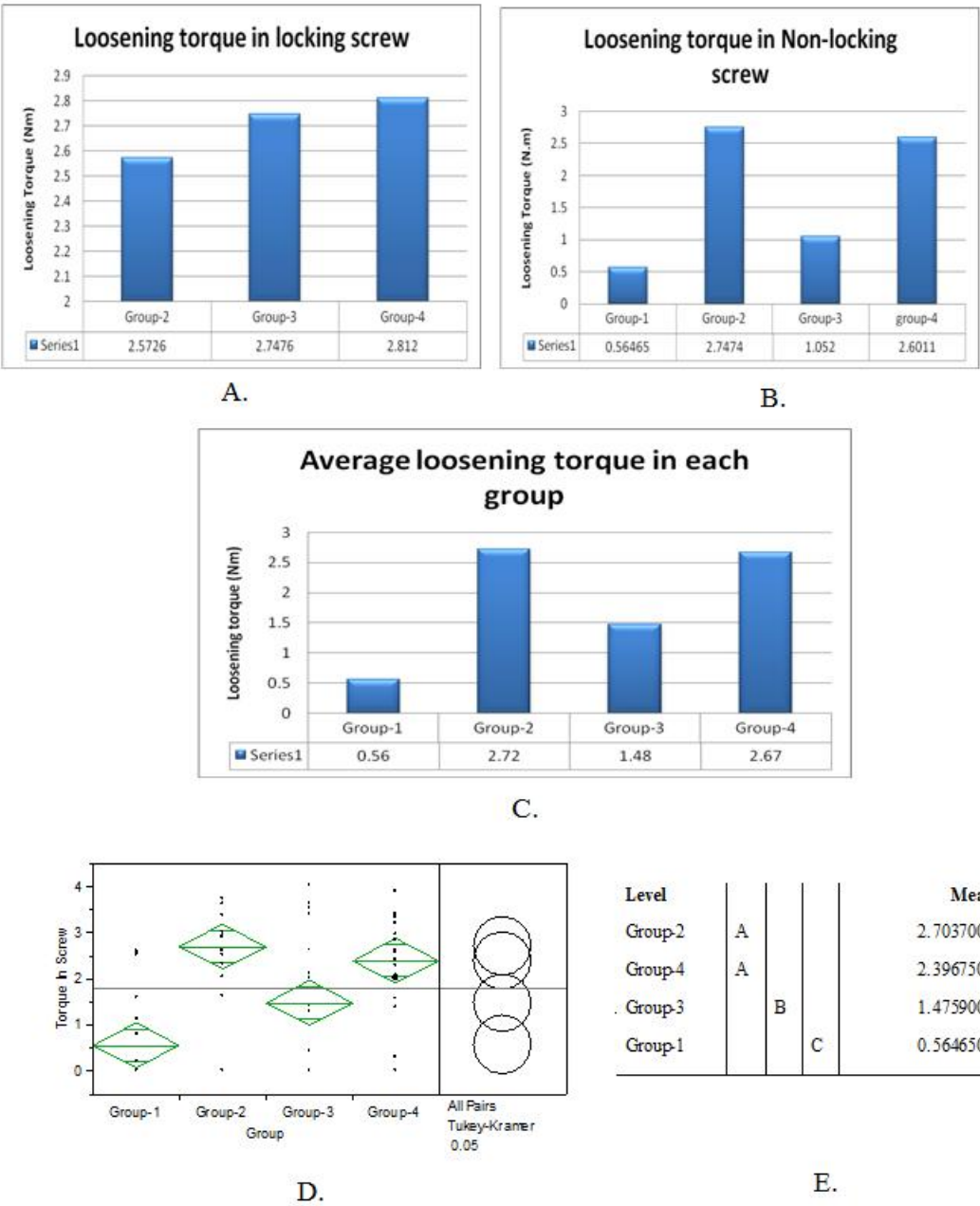


Figure 5.1: (A) Average loosening torque of locking screws in Groups 2, 3 and 4. (B) Average loosening torque of non-locking screws in all groups. (C) Average loosening torque for screws in each group. (D) Statistical results of obtained results for loosening torque.

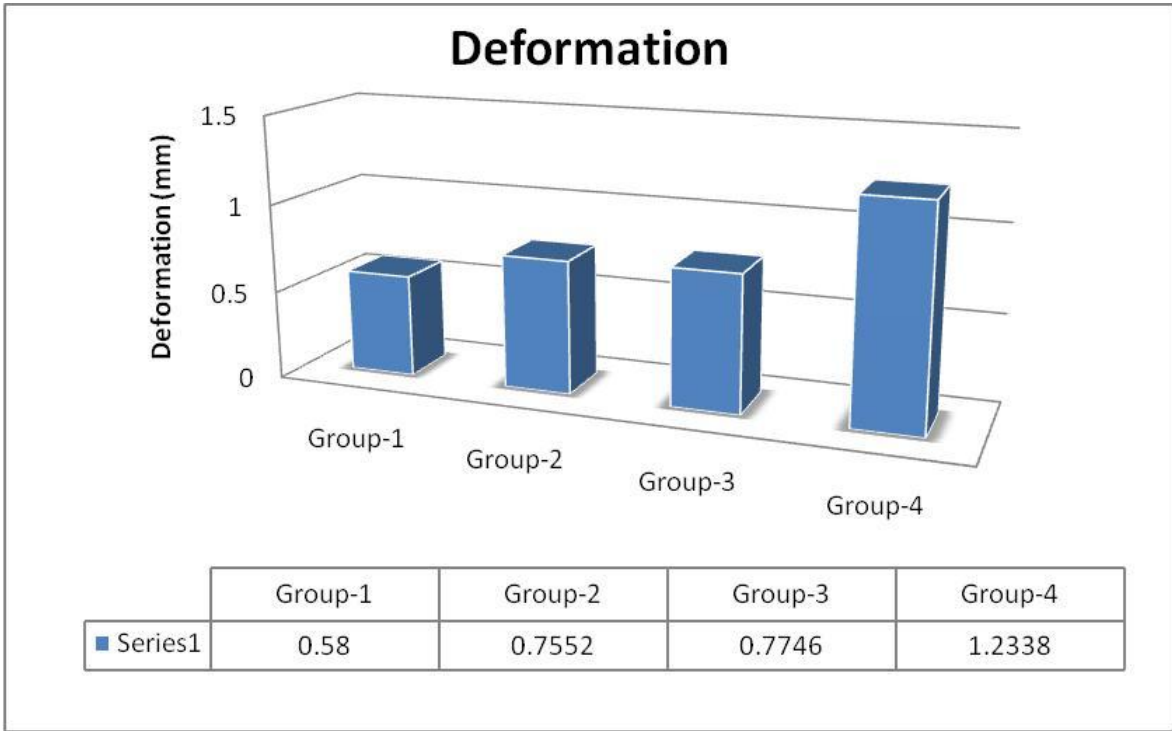
4. Group-4 with 2 non locking screws had minimum loosening 1.188 Nm (4 - 2.812) where group-2 with locking screw near osteotomy gap had maximum loosening 1.4274 Nm (4 - 2.5674). Figure 5.1(B) shows loosening in non-locking screws where loosening is seen maximum 3.4354 Nm (4 - 0.5647) in group-1 with all non-locking screw and minimum 1.2526 Nm (4 - 2.7474) in group-2. Difference of average loosening torque in non locking screw between group 2 and 3 is 43%.

5.2 Deformation

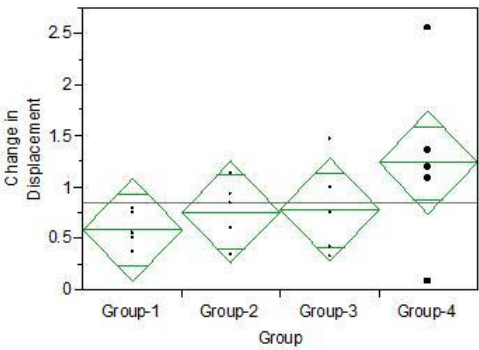
Before testing began, the initial actuator position was recorded. Tests results showed displacement of the actuator during the cycles. Deformation was measured by subtracting recorded displacement value from initial actuator position at interval of 5000 cycles. Table 5.2 and 5.3 show average deformation results for each femur constructs. Total deformation was measured by subtracting displacement value measured from recorded data at the end of the test and initial actuator position. Figure 5.2 shows the mean displacement of each group. Group-4 had the greatest mean displacement at 1.2338 mm. The non-locked construct (group-1) showed the lowest. Statistically results were verified as shown in Figure-5.2(B,C).

5.3 Axial and Torsional Stiffness

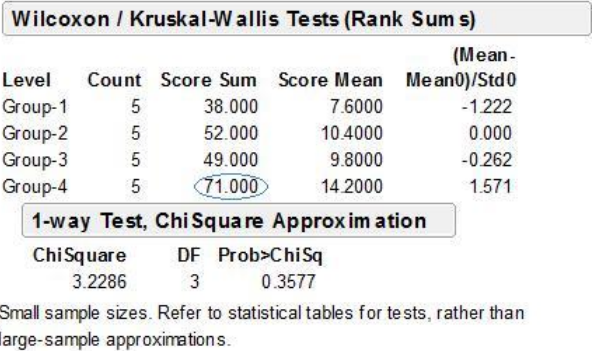
Axial and torsion average stiffness of the 20 femurs were calculated with applied load and displacement data at every 5000 cycles. Tables 5.2 and 5.3 show the average axial and torsional stiffness for every femur constructs. Average stiffness was calculated from the each femur's calculated average stiffness. Figure 5.3 shows the calculated average axial and torsion stiffness. Axial stiffness remains high 1231.315 N/mm in group-4 where smallest 745.34 N/mm in group-1. Torsional stiffness remains small in group-1 154.71 N/mm and highest in group-4 219.48 N/mm. Femoral stiffness varies because of deformation of the constructs. The mean stiffness was compared between groups statistically through the Kruskal-Wallis method. Statistical results in



A.



B.



C.

Figure 5.2: Average deformation for all femur constructs by group

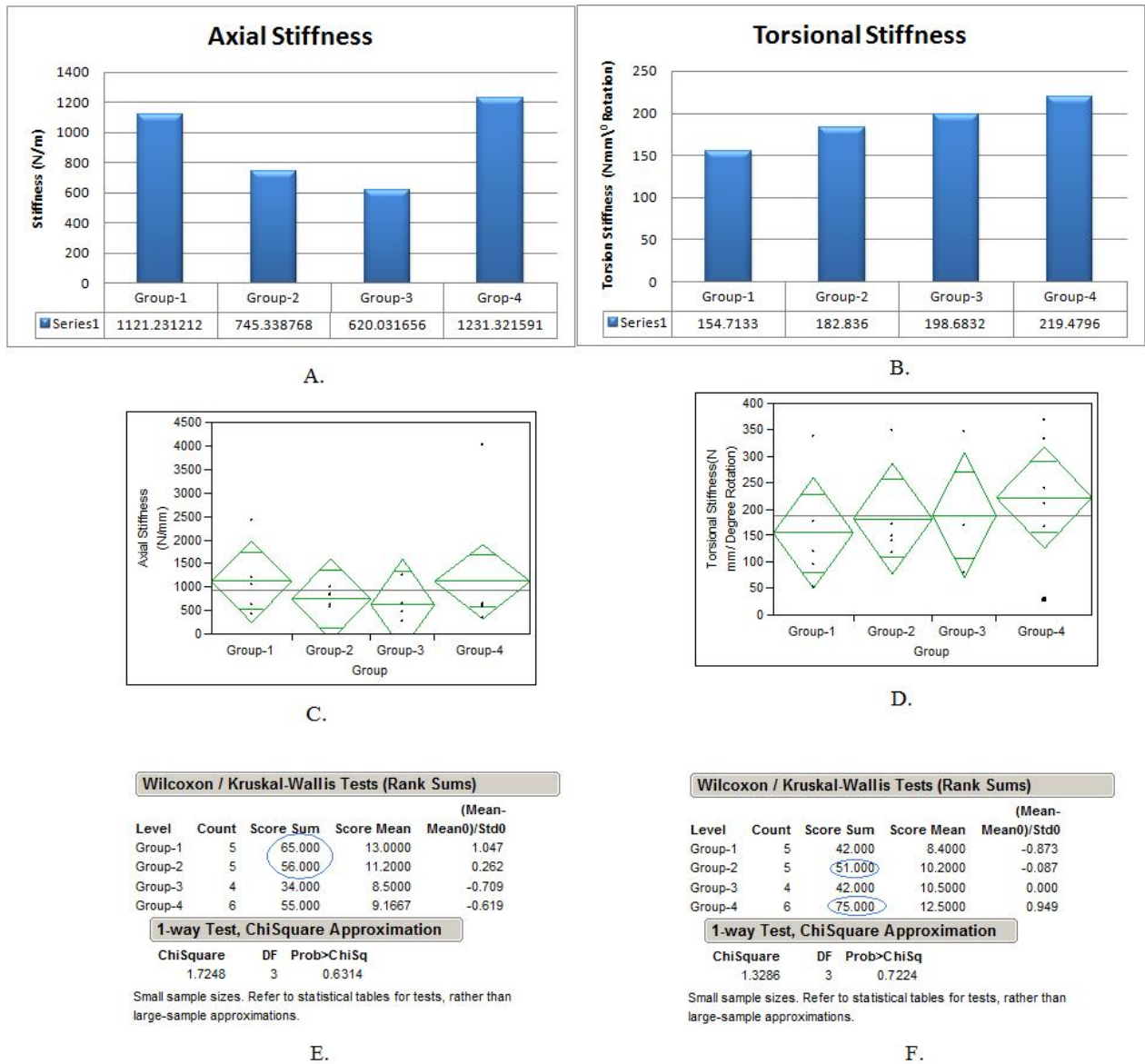
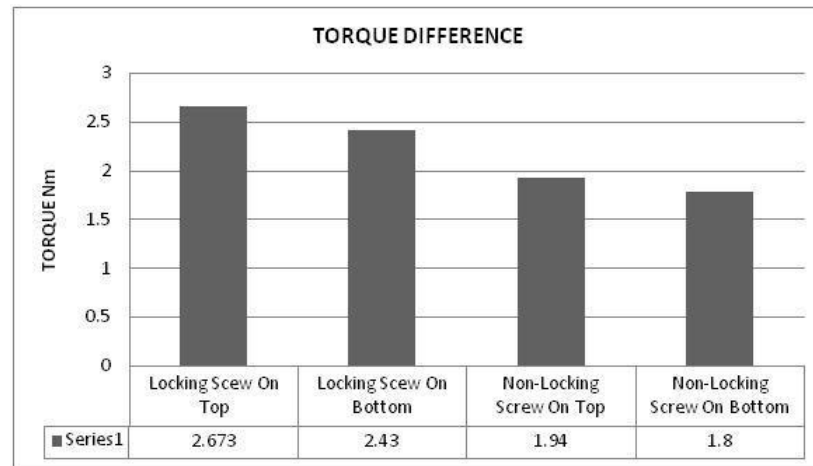


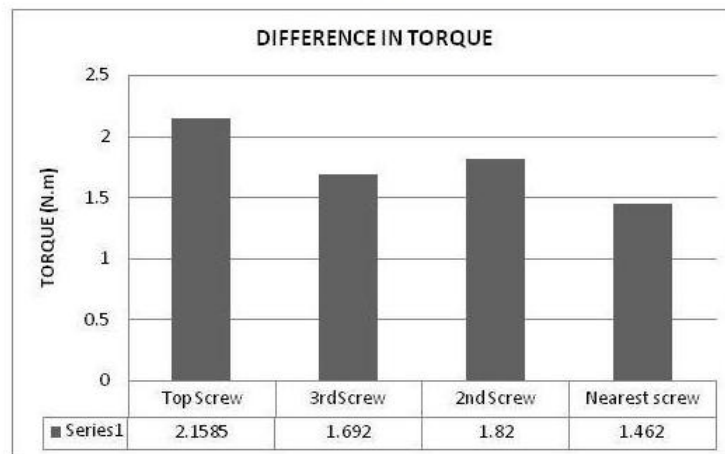
Figure 5.3: Axial and torsional stiffness calculated from the load and displacement data.

Figure 5.3(C,D) demonstrate that the average stiffness among all groups remains near the standard mean. Group-1 got highest score as shown in Figure 5.3(E) indicating highest mean stiffness where group-3 has lowest.

5.4 Loosening torque at different screw positions



A.



B.

Figure 5.4: (A) Average torque loosening for individual screw positions. (B) Loosening torque for locking and non-locking screws

Under rotational forces, loosening torque was compared for different screw positions from the osteotomy gap. Mean torque measured for all 4 screw positions (Farthest from osteotomy gap, screw-2, screw-3 and closest to osteotomy gap) as shown in Figure 5.4(A). Screws adjacent to the osteotomy gap maintained the lowest insertion torque with average torque of 1.462 Nm. Screws farthest away maintained greatest insertion torque with average torque of 2.1585 Nm. Screw-2 maintained more original insertion torque compared to screw-3. The Kruskal-wallis test demonstrated similar results with the highest average torque farthest from the osteotomy gap.

The average torque of locking screws farthest and closest from the osteotomy had been calculated separately to analyze loosening under axial and torsion loading conditions. Similarly the average torque of non-locking screws had been calculated. Figure 5.4(B) shows the comparison of all calculated average torque values. The locking screw farthest from the gap had a low loosening torque compared to locking screws closest to the fracture gap. In a similar way non-locking screws furthest from the gap showed low loosening torque compared to the non-locking screws nearer to the fracture gap. Also locking screws had a low loosening torque compared to non-locking screws. Finally locking screw closest to the fracture gap showed better torque than the closest non-locking screw.

5.5 Finite Element Analysis

Table-5.4 summarises the stress and displacement of various femur constructs as found in computational analysis by Ansys. Maximum stresses occurred in plates with more non-locking screws. Stresses were lowest in plates with locking screws. Maximum stress 427 N/m^2 occurred in plate with one locking screw and three non locking screws. Lowest stress 190 N/m^2 occurred in plate with 4 locking screws. Total displacement of locked construct was the minimum and was maximum for non-locked construct.

FEMUR CONSTRUCT	Stress (Mpa)	Displacement (m)
3 Non locking 1 locking	4.27	7.9
2 Non locking 2 locking	3.73	5
1 Non locking 3 locking	3.41	5.1
4 locking	1.9	3.8

Table 5.4: Results of Finite element analysis of the different screw plated constructs.

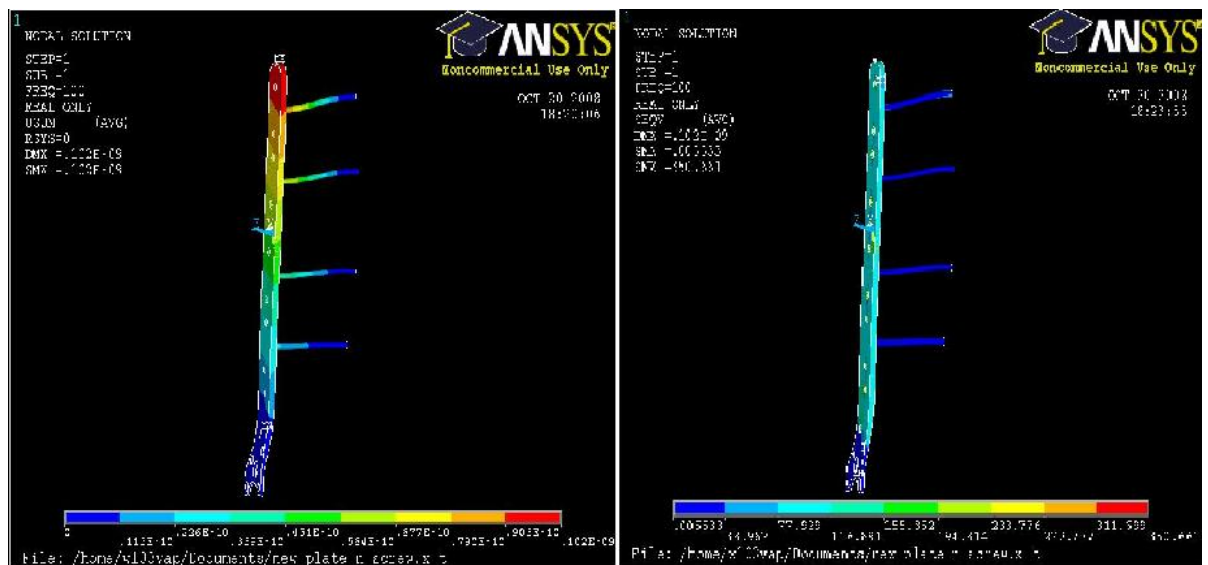


Figure 5.5: Displacement occurred due to axial load in plate (Left). Stresses induced in plate (Right).

5.6 Failure occurred during testing

Though all the experiments were statistically different, a few constructs failed catastrophically. In group-2 femur-3 the proximal femur shaft failed adjacent to the highest screw at the end of 50,000 cycles. Construct loosened at axial grip and slipped during rotational cycles. No effects were found in loosening torque in the screws (Figure 5.6).



Figure 5.6: Examples of catastrophic failures. The proximal shaft broke without affecting test (Bottom). Failure of Group-3 femur-3 where non-locked screw pulled out (upper right). Failure of group-1 femur-1. Three screws failed by breaking (upper left).

Three of the five femur constructs from group-1 failed. In group-1 femur-2, the highest non-locking screw disengaged from the bone. In group-1 femur-3, three screws failed as shown in Figure-5.6 and the intact screw pulled out. In group-1 femur-5, the lowest screw pulled out and remaining screw had 0 N m torque after the test. In

group-3, two femurs failed during testing. In group-3 femur-3 lowest screw failed and recorded 0 N m torque. The other failure in group-3 was femur 5 where the lowest screw pulled out. The remaining constructs successfully completed 50,000 cycles.

6

Discussion

Most studies provide evidence that locking plates with locking screws provides better stability under axial and torsion loading [3,7,9,53]. This information is of significant importance to clinicians for preoperation planning and to use an optimum combination of locked/non-locked screw plate constructs for fracture treatment. The parameters such as number of screws and where to place them to provide enhanced biomechanical properties are investigated in this research. Stoffel et al. [53] recommended screws to be placed near fracture gap when osteotomy gap was larger than 2 mm [53]. He also suggested working length (Distance between the first two screws on each side of osteotomy gap) to be kept minimum in larger fracture gap [53]. In case of torsion loading three to four screws in each fragment should be kept. Plate screw density is number of screws inserted divided by number of plate holes. Gautier et al.[52] suggested plate screw density to be 0.4 to 0.5 meaning half of the plate holes should be filled up with screws [52]. Use of bicortical screws in torsion load also increases stability. The AO/ASIF guidelines are not the pure applicable to decide number of screws. Considering all these studies, femur constructs used in experimental program were designed such a way that they should maintain plate screw density 0.5 (8/15) and each fragments should contain 4 screws on each side of fracture gap. Different than stoffel et al. study, screw positions were kept similar for all femur constructs. But they were categorized on the basis of screw types and order. In stoffel study, locked screw used for analysis whereas in this study locking and non

locking screws combinations were used. Fracture gap remained same for all groups and 20 femurs and composite femur shaft were expected to behave similarly under mechanical conditions.

Plot shown in Figure 5.1 was calculated to demonstrate average loosening of both locking and non-locking screws in each group. Result shows maximum loosening torque in group-1 by 84% than original and minimum in group-2 by 29.7% . Groups-2 and 4 have almost same average loosening torque and also they are statistically significant shown in the Tukey-cramer HSD results. Group-3 had non-locking screw near osteotomy gap which loosened the construct and that affected total average loosening torque. It had locking screw on top which maintained its torque but the other non-locking screw failed against the torsional loading. Group-1 with all non-locking screws demonstrated very poor stability and it had only 14% average torque remained after 50,000 cycles of the testing. Significant results between group-2 and group-4 implies that one locking screw near osteotomy gap was sufficient to provide stability under axial and torsion loads.

As per equation 6.1 torque is proportional to rigidity. Group-4 shows the highest rigidity because all the constructs in that group ran for 50,000 cycles without any screw failure. Three femurs in group-1 and 2 femurs in group-3 failed.

This results support equation 6.1 where angle of twist increases loosening torque. Top screw faces lower angle of twist. Similar results obtained for non-locking screws. So in any constructs with any locking screws or non-locking screws, screws near fracture gap need to be inserted with higher insertion torque. Inserting non-locking screw with higher insertion torque in osteoporotic bone may cause stripping. Stripping torque is the maximum torque which a bone can withstand [61]. Once screw reaches its stripping torque it starts to toggle in bone and can be easily pulled out. Non-locking screws have stripping torque of around 4.5 N-m in osteoporotic bones [4].

Biomechanical behavior of locking compression plate has been evaluated in various studies. But very few studies presented information about loosening torque and

pulling strength of screws and how they affect the LCP stability. As discussed in biomechanics of LCP, when non-locking screw was inserted, it generates reaction forces in opposite direction as well as reaction torque to applied insertion torque. When axial load was applied, the screw and plate construct maintains its stability until axial force was larger than reaction force. Locking screws behave differently because their stability does not depend on the bone material. Locking screw lock inside plate hole thread and resist axial and torsion loading by generating strong reaction forces in opposite direction. The pull out strength of non-locking screw depends on bone material property whereas pull out strength of locking screw depends on the insertion torque of screw. Therefore in osteoporotic bone locking screws provides extra stability.

This behavior was experimentally proven with the biomechanical testing results in this research. Loosening mechanics of locking screw and non-locking screw are different. So comparison between loosening torque for locking and non locking screws for different groups was done separately. Figure 5.1 shows average loosening torque in group-4 remains high because of two locking screw nearest and furthest from the osteotomy. It was minimum for Group-2 because of only one locking screw near osteotomy gap. Figure 5.1(B) shows average loosening torque of the non-locking screws. Group-1 has almost 80% loosening torque from the insertion torque whereas minimum loosening was seen in group-2. Group-2 and group-4 contained locking screw near the osteotomy gap. These results suggest that maximum loosening for locking screw is seen near osteotomy gap only. Locking screws near osteotomy gap loosened 8% more than locking screws furthest from the osteotomy gap. Non-locking screws near osteotomy gap loosened 52% more than non-locking screw furthest from the osteotomy gap. Therefore, locking screws near osteotomy gap can maintain more torque than non-locking screws. Figure 5.4 demonstrates similar results when average loosening torque near and away from osteotomy gap was calculated. Non-locking screws near osteotomy gap loosened 15% more than locking screw near osteotomy gap. These results support stoffel experiment that locking screws provide better

angular stability than non-locking screw. These results show that locking screws can resist more torsional load than non-locking screws and locking screw is recommended near the osteotomy gap than non-locking screw.

Equation 6.1 shows as the angle of twist increases loosening torque. Top screw faces lower angle of twist. Similar results obtained for non-locking screws. So in any constructs with any locking or non-locking screws, screws near fracture gap need to be inserted with higher insertion torque. Inserting non-locking screw with higher insertion torque in osteoporotic bone may cause stripping. This research demonstrates importance of insertion torque by correlating it with other mechanical parameters namely stiffness, rigidity and deformation. As per equation 6.1, torsion rigidity (GJ) was proportional to insertion torque of the screw. As insertion torque decreases, rigidity of the construct starts to decrease resulting in reduced screw holding power of the constructs. Screws start to toggle and affect the stability of LCP under both axial and torsion loading.

$$\frac{T}{J} = \frac{\tau}{R} = \frac{G\Phi}{l} \quad (6.1)$$

where,

- T= torque Nm
- J= the torsion constant for the section
- τ = the maximum shear stress at the outer surface.
- R= the outer radius of the shaft.
- G= the shear modulus
- Φ = the angle of twist in radians.
- l= the length of the object the torque is being applied to or over.
- GJ= the torsional rigidity

$$T = \left(\frac{GJ}{l}\right)\phi \quad (6.2)$$

$$k = \frac{GA}{l} \quad (6.3)$$

$$T = kA\Phi \quad (6.4)$$

Where,

k = Stiffness.

A= area where force applied

Gardner et al. performed mechanical study on osteoporotic humerus sawbones [57]. They applied oscillating cyclic torsion of 10 N-m for 1000 cycles and measured stiffness in conventional, locking and hybrid plates. Results suggest that hybrid plates got similar stiffness after 1000 cycles to LCP plates [57]. In another study [58], the author applied 500 N compression and 10 N-m torsion on hybrid locking plates and locking plates. Their results showed torsional stiffness and torsional rigidity of the locking constructs were similar to the average of the hybrid construct. Both hybrid construct and locking construct exceeded average stiffness by 23% and 53%, respectively, to non-locking construct. Similar results were obtained in this study. Two locking screws construct had maximum torsion stiffness among all groups. Average axial stiffness of the plot shown in Figure 5.3 is not showing appropriate results because of the random load and displacement data but it suggests that axial stiffness of group-4 has highest stiffness. Thus stiffness is co-related with torque of the screw. Relation between stiffness and torque is shown above. So as torque in the screw increases, it lowers the stiffness of the constructs.

Limited data was available on deformation of locking plates under axial and torsion loading. Gautier discussed that in small fracture gap higher displacement caused plate bending with locking screws inserted and screw pull out may occur in non-locking screws [52]. Deformation depends on the change in length and load applied. Some deformation allows flexibility in locking plates that leads to increase in the

callus formation. If deformation leads to fracture than, two fracture fragments come close, increasing chance of failure. Sikes et al. studied displacement between locking head screw and conventional screw [59]. He tested bones under load displacement of 150 N. His results [59] showed increased resistance in two locking head construct compared to two conventional screw construct. When same test applied to four screw construct with both type of screws, no significant differences were found. Results shows maximum deformation in group-4 and group-1 showed minimum deformation. Deformation in locking screws seen higher because of the pitch and radius of the locking screws were smaller than non-locking screws. It increases the change in length which allows more strain to be developed. This phenomenon allows more callus formation in vivo and heals the osteotomy quickly. Initially increased deformation was seen because of small cracks remained inside osteoporotic bone. Under compression load these cracks got filled up and allowed more deformation early on. But as loading continued, new cracks start to propagate and additional deformation is seen with cycling.

FEA studies to support experimental results were compared. As per equations-(6.1-6.4), stiffness increases with the insertion torque. Results of the FEA suggest that construct with locking screw is lot stiffer and induced very low stresses compared to other constructs. In FEA, only axial load was applied. Axial stiffness also remains high for locked construct because of higher displacement.

Use of hybrid plate is becoming popular among clinicians. Recent studies suggest that under both axial and torsion conditions, stiffness and displacement of LCP remains the same for Hybrid and locked constructs [62, 63, 64]. We used 20 femur constructs with hybrid screw placement, and results obtained suggest that use of locking constructs provide better angular stability than hybrid constructs.

7

Concluding Remarks

Experimental testing and analytical evaluation of locking compression plate with both locking and non-locking screws support the thesis hypothesis that construct with locking screws perform better than construct with non-locking screws both analytically and experimentally. During conduct of experimental program, several new behaviors of LCP have been derived, summerized below.

1. Loosening of the locking screws was seen minimum near the osteotomy gap compared to the loosening of the non-lcoking screws. Locking screws increase the torsional rigidity of the adjacent non-locking screws. This allows surgeons to put second locking screw away from the first locking screw in long plates to maintain construct stable.
2. In hybrid plated constructs, construct with two locking screw showed minimum loosening, incresed stiffness and deformation than constructs with one locking screw and all non-locking screws. One locking screw near osteotomy gap provides necessary axial stiffness and torsional rigidity against both axial and torsion loading. Use of more than one locking screw in construct does not affect biomechanical results.
3. Insertion torque of all screws must be maintained to 4 N-m for normal bone. In osteoporotic bone stripping torque should be considered before inserting non-locking screw. Screws near osteotomy gap can be tightened up more as loosening

was observed more in those area.

4. Deformation among locking screw constructs was seen more than non-locking screw constructs. This increases the flexibility of the construct and expected to increase callus formation in-vivo.
5. Torsional Stiffness was high in locking constructs. Also torque remained high in locking constructs. As torsional stiffness is directly proportional to torque, these results were expected.
6. Induced stresses were minimum and displacement was maximum on locking plates than on non-locking plates shown in the finite element analysis results.
7. The constructs prepared with locking screws were able to perform under various loading conditions while maintaining the stability of entire construct.

7.1 Future Work

This biomechanical study will be helpful to surgeons in pre-operating planning. Further investigations are required for in-vivo/in-vitro use of LCP and their biomechanical behaviors. Analytical modeling of medical prostheses with the help of CT images are important though difficult to design complex geometry of bones with existing software. CT images and image processing technique will be useful to develop 3D models with complex geometrical shapes and their further investigation with FEA. These new results from biomechanical and computational analysis will reduce time, and cost of complex experimental tests.

8

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